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10/780,435	02/17/2004	Robert D. Kross	K15-007.CIP/K15-017	1559

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EXAMINER

ISSAC, ROY P

ART UNIT	PAPER NUMBER
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1623

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/780,435

Applicant(s)

KROSS ET AL.

Examiner

Roy P. Issac

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Status of the Application

This application is a CIP of 10/041,310 filed 01/07/2002 (abandoned) and claims benefit of 60/511,916 filed 10/17/2003.

This Office Action is in response to Applicant's amendment/ remarks/ response filed 12/26/2006, wherein claims 1, 4, 5, and 6 were amended. Claims 1-20 are currently pending, and under examination on the merits herein.

Rejections Withdrawn

The rejection under 35 U.S.C § 112, second paragraph with respect to the lack of antecedent basis for the phrase "relatively constant", of claims 1-20, is withdrawn, since said phrase has been deleted.

The rejection under 35 U.S.C § 112, second paragraph with respect to the lack of antecedent basis for the phrase "surface active material", of claim 4, is withdrawn, since said phrase has been deleted.

The rejection under 35 U.S.C § 112, second paragraph with respect to the lack of antecedent basis for the phrase "comparable", of claim 5, is withdrawn, since said phrase has been deleted.

The rejection under 35 U.S.C § 112, second paragraph with respect to the lack of antecedent basis for the phrase "five minutes or more", of claim 6 (typographical error in previous office action indicating claim 8), is withdrawn, since said phrase has been deleted.

The following are new or modified rejections necessitated by Applicant's amendment filed 12/26/2006, wherein the limitations in pending claims 1-20 as

Art Unit: 1623

amended now have been changed since claims 1, 4, 5 and 6 has been amended and claims 2-20 depends from amended claims. The limitations in the amended claims have been changed and the breadth and scope of those claims have been changed. Therefore, rejections from the previous Office Action, filed 08/30/2006, have been modified and are listed below.

Claim Objections

Claims 12 and 13 are objected to because of the following informalities: Claims 12 and 13 recites "a method of claim 1." However, claim 1 is directed to a composition. Appropriate correction is required.

Response to Arguments

Applicant has not addressed the objections with respect to claims 12 and 13 in the response filed dated 12/26/2006.

The claims are deemed properly objected and is adhered to.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a

Art Unit: 1623

way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's amendment with respect to amended claims herein has been fully considered but is deemed to insert new matter into the claims since the specification as originally filed does not provide support for a "wherein the percent by weight of said metal nitrite in said composition ranges from about 0.01 to about 1.0". The original specification clearly discloses doses of "less than about 1.0, preferably about 0.01 to about 0.75, more preferably 0.03 to about 0.70, and even more preferably from about 0.05 to about 0.50 percent by weight of metal nitrite." (Specification, Page 11, Paragraph 2). The range now claimed "about 0.01 to about 1.0" is considered to the subgenus range of "less than about 1.0" as originally described. The Court of Appeals for the Federal Circuit held that "subgenus range was not supported by generic disclosure and specific example within the subgenus range"; See, e.g., *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971); the court also held that "a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads" (see *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972). See also MPEP 2163. Consequently, there is nothing within the instant specification which would lead the artisan in the field to believe that Applicant was in possession of the invention as it is now claimed. See *Vas-Cath Inc. v. Mahurkar*, 19 USPQ 2d 1111, CAFC 1991, see also *In re Winkhaus*, 188 USPQ 129, CCPA 1975.

Art Unit: 1623

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation "stabilized" is not clearly defined in the specification and it is not clear how and what way the composition is stabilized.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Benjamin et. al.(Of Record).

Benjamin et. al. discloses acidified nitrite as an antimicrobial agent. (Page 1, lines 3-4). Benjamin et. al. further discloses that the acidification of nitrite produces nitrous acid. (Equation 1, Page 1, line 36). Benjamin et. al. discloses the use of nitrites below pH 4 and the use of metal nitrate as precursor for nitrite ions. (Page 3, lines 20-25). Benjamin et. al. discloses the use of acidified nitrites

Art Unit: 1623

in carriers such as cream or ointment. (Page 3, lines 27-30). Note that ointment and cream are considered as gel. The acidified nitrite is disclosed for use in either liquid or tablet form. (Page 3, lines 35-36). Benjamin et. al. further discloses a method for sterilizing using acidified nitrite. (page 4, lines 1-10). Benjamin et. al. further discloses the use of citrate/phosphate buffer in which sodium nitrite was added to produce an acidified nitrite solution. (Page 5, Example 1). Benjamin et. al. further discloses the use of acidified nitrite solution against E.Coli. (Page 6, Example 2, lines 20-23). Benjamin et. al. discloses that 1mM concentration of nitrite solution can kill E.Coli completely. (Page 7, Example 3, lines 7-8). Benjamin et. al. further discloses the use of salicylic acid and sodium nitrite on patient feet with fungal infection. (Page 7, Example 5, lines 33-37). Note, that feet is considered mammalian tissue. Benjamin et. al. further discloses the use of acidified nitrites as mouthwash. (Page 8, Example 6, lines 8-14). Benjamin et. al. further discloses the sue of nitrite solution for sterilizing objects such as dentures. (page 2, lines 32-35). Note that, objects such as dentures are considered to have some partial metal surfaces. Since Benjamin et. al. discloses the use of citrate-phosphate buffer, a well known buffer in acidic conditions, it is expected to keep the pH relatively constant and thus keep the cidal activity of the acidic nitrite solution for two months or longer even twenty-four months. The 0.5 to 30% metal nitrite disclosed falls within the 0.01 to 1.0 range claimed herein. (Claim 12; Column 9).

The recitations, "the composition exhibits cidal activity against microorganisms for a period of two months after formulation," "wherein the cidal

Art Unit: 1623

activity of the composition over a period of about twenty four months or more after formulation is comparable to the activity that it demonstrated initially," and wherein the cidal activity of the composition over a period of about five minutes or more after formulation is equivalent to the activity necessary to achieve an approximately eight log decrease in a sample of E.Coli" are considered functional recitations or inherent properties. The prior art compositions discussed above are expected to show such functional properties because they are deemed to be the same compositions comprising same ingredients.

Response to Arguments/ Amendments

Applicants' arguments filed 12/26/2006 with respect to this rejection of claims 1-20 under 35 U.S.C. 102(b), of record in the previous Office Action have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art as further discussed below.

Applicants argue that the compositions of Benjamin et. al. teaches the criticality of separation of acid and nitrite before direct use, and the presence of nitrogen oxides for the germicidal action. The claims herein are not limited to nitric oxide or nitrogen dioxide. The claims herein are directed to a composition comprising nitrous acid, a metal nitrate and an alpha hydroxyl acid or phosphoric acid, and a method comprising treating infection using the same. Whether Benjamin et. al. recognized the reason for bactericidal effect of the composition is immaterial. Under the principles of inherency, if a prior art device or method, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be anticipated by the prior art device or method. *In*

Art Unit: 1623

Re King 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986). "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In *In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004). See MPEP 2110.4. Applicants arguments appears to try distinguishing the disclosure of the prior art with the intended use of the composition. A composition that is kept separately is not the only embodiment disclosed in Benjamin et. al. As noted in the previous office action, Benjamin et. al. discloses the use of acidified nitrites in carriers such as cream or ointment. (Page 3, lines 27-30). Clearly, those are compositions intended for long-term use. Note that it is well settled that "intended use" of a composition or product will not further limit claims drawn to a composition or product, so long as the prior art discloses the same composition comprising the same ingredients in an effective amount, as the instantly claimed. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. Applicants further argue that Benjamin et. al. teaches the criticality of separation of two acid and nitrite. However, Benjamin et. al. discloses the mixing of these two ingredients. The claims herein are directed to a composition which is disclosed in Benjamin. As discussed above, under the principles of inherency, it is immaterial whether

Art Unit: 1623

Benjamin recognized that the mixed composition is capable of long term use. As such, the claims are deemed properly rejected under 102(b) and is adhered to.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

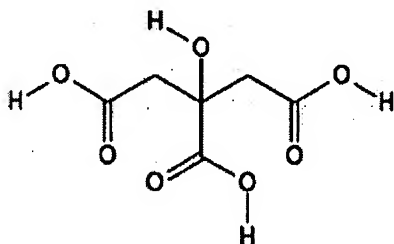
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xu et. al. (Of Record), in view of Kross et. al. (Of Record) further in view of Benjamin et. al. (Of Record)

Xu et. al. discloses the use of nitrite in citric acid-phosphoric acid buffer (pH 3.3 and 2.5) as an antimicrobial agent. (Abstract and Page 524, Column 2, Paragraph 3). Xu et. al teaches that citric acid and nitrite are present in gastric juices and nitrite is present in saliva. (Page 524, Column 1, paragraph 1). Note that applicant defines "nitrite" or "nitrite salt" as a salt of nitrous acid. (Page 5, Second paragraph under "Detailed description of the invention). The specification shows the ratio of nitrous acid to nitrite under various pH conditions. (Table 1, Page 8). Specification shows that at pH 3.3, the ratio of nitrous acid to nitric acid is 1:1 (50% HNO_2 and 50% NO_2^-). (Table 1, Page 8). The ratio is 83.3 to 16.7 Nitrous acid:Nitrite at pH 2.3. (Table 1, Page 8). The protonation of dissolved nitrite ions under low pH conditions produces nitrous acid. Xu et. al.

Art Unit: 1623

teaches that nitrite in pH 3.3 phosphate-citrate buffer has bactericidal effect against E-Coli. (Page 525, Column 2, Paragraph 1 and Table 1). Xu et. al. reports a reduction in E-Coli count on the log scale of 7.18 to less than 1 in 3 hours. (Table 1, 10mg Nitrite, Citrate-phosphate buffer). Xu et. al. further reports significant decreases in microbial count after treatment with nitrite solution in citrate-phosphate buffer at pH 2.5. (Page 526, Table 3). Even though Xu et. al. does not report the long term pH variability of the nitrite solution, it is expected to remain stable because citrate-phosphate is a strong buffer in acidic conditions. As such, the recitation "the pH of the composition either remains relatively constant at an initial value of around 3.75 or lower, or decreases from said initial value of around 3.75 or lower at the time of formulation to a value as low as around 2.5 over a period of at least about two days, preferably about two days to five days;" is considered a description of an inherent property of the nitrite solution in citrate-phosphorous buffer at pH 3.3. Since the composition is in a buffer, it is considered "stabilized". Note that citric acid (structure shown below) is has the alpha hydroxyl acid structure of claim 3.



Xu et. al. describes the use of agar which is considered as a thickener. (Page 524, Column 1, last paragraph). The buffer solution of Xu et. al. is considered an "application medium" recited in claim 7. This phrase "about" is interpreted to

Art Unit: 1623

include 0.0050% in the "about 0.01 to about 1.0" range claimed herein. Note that, the recitations "wherein the composition may be sprayed onto a substrate, " "teat dip" and "wherein the composition is an oral rinse" are considered as intended uses of the composition. Note that it is well settled that "intended use" of a composition or product, will not further limit claims drawn to a composition or product, so long as the prior art discloses the same composition comprising the same ingredients in an effective amount, as the instantly claimed. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

Xu et. al. does not expressly disclose the use of metal nitrite to generate nitrous acid or the composition in the form of a teat dip or gel or a gel with a thickener or the methods of disinfecting a substrate or method of disinfection of a substrate over a period of several months.

The disclosure of Benjamin et. al. is discussed above.

Kross et. al discloses the use of antimicrobial agents to disinfect meat carcass. (Abstract). Kross et. al. notes that "Thus, there is a continuing need for an effective and safe spray disinfectant to apply to animal carcasses soon after the evisceration process, before contaminating organisms can develop a firm foothold on the meat surfaces." Kross et. al. discloses the use of low pH antimicrobial agents containing citric acid. (Column 2, example 1). Kross et. al. further discloses the use of phosphoric acid with pKa of 2.15. (column 3, lines 40-45).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a metal nitrite, in particular ranges as claimed herein

Art Unit: 1623

in a composition that comprise an alpha hydroxyl acid or phosphoric acid, both well known buffers to make a stabilized composition and to use said composition as disinfectant containing nitrite to clean surfaces because Xu et. al. discloses the usefulness of nitrites in low pH solutions as antibacterial agents and Kross et. al. discloses the use of antibacterial agents to disinfect meat surfaces and Benjamin et. al. discloses the specific ranges of metal nitrites.

One having ordinary skill in the art would have been motivated to do this because Kross et. al. discloses the need for effective and safe disinfectant and Xu et. al. teaches that nitrites are naturally present in gastric juices and saliva and are effective antibacterial agents.

As such one of ordinary skill in the art would have reasonably expected a composition comprising a metal nitrite and an alpha hydroxyl acid or phosphoric acid would have resulted in a stabilized solution with similar or better antimicrobial activity.

Response to Arguments/ Amendments

Applicant's arguments/amendments filed 12 December 2006 have been fully considered but they are not persuasive.

Applicants note in reference to Xu et.al. that, "at those specific conditions, the authors conclude that the observed bactericidal effects were not primarily related to nitric oxide and nitrogen dioxide." The claims herein are not limited to nitric oxide or nitrogen dioxide. The claims herein are directed to a composition comprising nitrous acid, a metal nitrate and an alpha hydroxyl acid or phosphoric

Art Unit: 1623

acid, and a method comprising treating infection using the same. Whether Xu et. al. recognized the reason for bactericidal effect of the composition is immaterial. Under the principles of inherency, if a prior art device or method, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be anticipated by the prior art device or method. *In Re King* 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986). "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In *In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004). See MPEP 2110.4. Applicants further notes that, "Indeed Xu, et. al., discloses nitrite levels *far below* that of the present invention". Applicants note that the levels of metal nitrite disclosed in Xu et. al. is 0.00050% - 0.0050%. (Applicants response, Page 11). This phrase "about" is interpreted to include 0.0050% in the "about 0.01 to about 1.0" range claimed herein.

In regards to applicants arguments in reference to Kross et. al., applicant is reminded that Kross was used in combination with Xu et. al. in an obviousness rejection. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See

Art Unit: 1623

In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, Kross et al. has been cited as a secondary reference for its teaching that the low pH antimicrobial agents in particular using citric acid to achieve low pH to disinfect meat.

Conclusion

No Claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1623


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy P. Issac whose telephone number is 571-272-2674. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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